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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,511	06/30/2004	Stephen Francis Badylak	3220-72178	6418

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BARNES & THORNBURG LLP
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INDIANAPOLIS, IN 46204

EXAMINER

CHEN, SHIN LIN

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

04/20/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

indocket@btlaw.com

Office Action Summary

Application No.

10/500,511

Applicant(s)

BADYLAK ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 1-10 and 16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11-15 and 17-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Applicant's amendment filed 2-2-10 has been entered. Claims 1-19 are pending. Claims 11-15 and 17-19 are under consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 11-15 and 17-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Badylak, Stephen, 2002 (US Patent No. 6,379,710 B1, IDS-AG) or Badylak, Stephen, 1998 (WO 98/25637) each in view of Badylak et al., 2007 (US Patent No. 7,175,841 B2) and is repeated for the reasons set forth in the preceding Official action mailed 11-2-09. Applicant's arguments filed 2-2-10 have been fully considered but they are not persuasive.

Applicant argues that Badylak (2007) describes the DNA content of cartilaginous tissue formed on an intestinal submucosa and the DNA content is an estimated quantification of cartilaginous tissue grown in vitro on intestinal submucosa by correcting for the intestinal submucosa contribution. The cited 0.86 ± 0.2 ug DNA/mg dry weight is irrelevant compared to the DNA content of the instant invention. The DNA content of intestinal submucosa as disclosed by Badylak (2007) (2.04 ± 0.1) does not overlap the claimed range of the DNA content (0.303 ± 0.263). The method taught by Badylak (2002) and Badylak (2007) result in graft constructs with a DNA content higher than the claimed DNA content of the instant invention. It is not obvious from the teachings of the prior art that a skilled artisan could achieve the DNA purity level claimed in the instant invention (amendment, p. 5-9). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-2-09. Basement membrane is composed of lamina densa and lamina lucida, which consist of type IV collagen, proteoglycan, laminin, integrin, and dystroglycans etc. Intestinal submucosa is the layer of dense irregular connective tissue that supports mucosa, and it contains blood vessels, lymphatic vessels, nerves, accessory salivary glands and connective tissues, which contains collagen. A cartilaginous tissue contains chondrocytes that produce a large amount of extracellular matrix composed of type II collagen, abundant ground substances rich in proteoglycan and elastin fibers, but no blood vessels. It appears that cartilaginous tissue is more close to basement membrane than intestinal submucosa in view of its composition. Thus, the DNA content of the cartilaginous tissue is more representative to the claimed liver basement membrane than that of intestinal submucosa. DNA content of 0.86 ± 0.2 ug DNA/mg dry weight is very close to the claimed 0.303 ± 0.263 ug DNA/mg dry weight. Further, Badylak (2002) teaches preparation of a liver basement

membrane composition, and determining the DNA content of the liver basement membrane and to have various different DNA contents in various liver basement membranes would be obvious to one of ordinary skill. Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to prepare a liver basement membrane graft composition comprising basement membrane having DNA content of 0.303 ± 0.263 ugDNA/mg dry weight of basement membrane in view of the teachings of Badylak (2002), Badylak (WO 98/25637) and Badylak (2007).

4. Claim 19 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al., 1980 (European Journal of Biochemistry/FEBS, Vol. 111, No. 2, pp. 485-490) in view of Badylak et al., 2007 (US Patent No. 7,175,841 B2) and is repeated for the reasons set forth in the preceding Official action mailed 11-2-09. Applicant's arguments filed 2-2-10 have been fully considered but they are not persuasive.

Applicant reiterates the argument that the range of the DNA content of basement membrane as claimed does not overlap with the range of the DNA content of the intestinal submucosa composition as described by Badylak and they do not have same properties. The combination of either Robinson or Brendel in view of Badylak (2007) fails to uphold a rejection based on 35 U.S.C. 103(a). None of the cited references suggest a DNA content that is within the claimed range (amendment, p. 9-11). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-2-09 and the reasons set forth above.

5. Claim 19 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al., 1980 (Advances in Experimental Medicine and Biology, Vol. 131, pp. 89-103) in view of Badylak et al., 2007 (US Patent No. 7,175,841 B2) and is repeated for the reasons set forth in the preceding Official action mailed 11-2-09. Applicant's arguments filed 2-2-10 have been fully considered but they are not persuasive.

Applicant reiterates the argument that the range of the DNA content of basement membrane as claimed does not overlap with the range of the DNA content of the intestinal submucosa composition as described by Badylak and they do not have same properties. The combination of either Robinson or Brendel in view of Badylak (2007) fails to uphold a rejection based on 35 U.S.C. 103(a). None of the cited references suggest a DNA content that is within the claimed range (amendment, p. 9-11). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 11-2-09 and the reasons set forth above.

Conclusion

No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Art Unit: 1632

Shin-Lin Chen, Ph.D.

/Shin-Lin Chen/

Primary Examiner

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